

COPPERTONE DEFEND AND CLEAR- octinoxate, octisalate, zinc oxide lotion
Beiersdorf Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

D&C Clear Zinc Face SPF 50

Drug Facts

Active ingredients

Octinoxate 7.5%, Octisalate 4.5%, Zinc Oxide 9.7%

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well before use
- apply liberally 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer

and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces

Inactive ingredients

water, dicaprylyl ether, glycerin, polyester-27,styrene/acrylates copolymer, trilaureth-4phosphate,cetearylalcohol,beeswax,dimethicone, ammonium acryloyldimethyltaurate/VP copolymer, benzyl alcohol,glyceryl stearate, triethoxycaprylylsilane, chlorphenesin, disodium EDTA

Questions?

1-866-288-3330

Principal Display Panel

Coppertone Sunscreen Lotion

Clear Zince FACE

with Zinc Oxide

Defend & Care

Lightweight No White Residue

Free of oxybenzone, dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

3 FL OZ (88 mL)

Coppertone Defend & Care™ helps protect skin against the sun's most damaging UVA/UVB rays – in a breakthrough zinc oxide-based lotion that rubs in clear with no white residue. Its proven sun protection in a lightweight formula helps maintain vibrant, healthy-looking skin.



Clear Zinc Face Sunscreen

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Questions? 1-866-288-3330

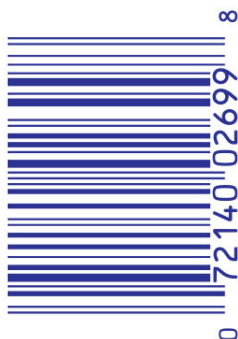
Beiersdorf

Beiersdorf Inc. Wilton, CT 06897

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Coppertone®
SUNSCREEN LOTION

Clear Zinc

FACE

WITH ZINC OXIDE

Defend & Care

Lightweight

No White Residue

50

FREE OF oxybenzone, dyes & PABA

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50

3 FL OZ (88 mL)

COPPERTONE DEFEND AND CLEAR

octinoxate, octisalate, zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66800-3641

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.7 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
POLYESTER-7 (UNII: 0841698D2F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800-3641-3	88 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	
2	NDC:66800-3641-6	177 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2020	

Labeler - Beiersdorf Inc (001177906)

Establishment

Name	Address	ID/FEI	Business Operations
Beiersdorf Manufacturing, LLC		117138167	analysis(66800-3641) , label(66800-3641) , manufacture(66800-3641) , pack(66800-3641)